(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 635 274 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
17.03.1999 Bulletin 1999/11

(51) Int. Cl.[6]: **A61L 15/00**, C08J 5/00, C08K 5/00

(21) Application number: **94111052.0**

(22) Date of filing: **15.07.1994**

(54) **Method of making surgical sutures**

Verfahren zur Herstellung chirurgischen Nahtmaterials

Procédé de préparation de sutures chirurgicales

(84) Designated Contracting States:
DE FR GB IT

(30) Priority: **21.07.1993 US 95789**
09.12.1993 US 164510

(43) Date of publication of application:
25.01.1995 Bulletin 1995/04

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(56) References cited:
US-A- 4 201 216
US-A- 4 532 929
US-A- 4 983 180

- **DATABASE WPI Section Ch, Week 9242 Derwent Publications Ltd., London, GB; Class A23, AN 92-345087 XP002006856 & JP-A-04 249 527 (TAKI CHEM CO LTD) , 4 September 1992**

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Description

Field of the Invention

[0001] The present invention relates generally to sutures.

Background of the Invention

[0002] Plasticizers are molecules that when mixed with polar or hydrogen bonded polymers position themselves between the intermolecular bonds, thus increasing the spacing between adjacent bonds. In this manner, plasticizers lower the strength of the intermolecular forces, thus increasing the flexibility of the polymeric structure. For example, PVC, which is polar, is plasticized by substances such as dioctylphthlate. As another example, nylon, which is hydrogen bonded, is plasticized by water. Derivatives of long chain fatty aliphatic acids such as lauric, palmitic, stearic or behenic acid have been identified as spinning aids for polyamide fibers. (See, U.S. Patent No. 3,516,956). Since the softening effect of plasticizers is equivalent to increasing extrusion temperatures, extruding plasticized polymers will require lower temperatures for comparable melt viscosities. Thus, the danger of thermal degradation of the polymer is generally decreased by employing a plasticizer. In this respect plasticizers are, indirectly, thermal stabilizes.

[0003] Absorbable surgical devices have been made from fibers of synthetic polymers such as polymer made from glycolide, lactide or p-dioxanone. With respect to polyglycolic acid sutures, U.S. Patent No. 3,297,033 states at column 3, line 45 that: "In general, plasticizers tend to interfere with crystallinity, orientation, etc., and weaken fibers, but are useful for sponges and films." U.S. Patent No. 3,792,010 describes plasticized polyester sutures prepared by reacting glycolide and lactide in the presence of a plasticizer such as bis-2-methoxyethyl phthalate or acetoxytriethyl citrate. U.S. Patent No. 3,636,956 states at column 7, line 9 that any of a variety of plasticizers such as glyceryl triacetate, ethyl benzoate and diethyl phthalate can be used with polylactide and that preferred plasticizers for glycolide/lactide copolymers are dibutylphthalate and bis-2-methoxyethyl phthalate. U.S. Patent No. 4,915, 893 describes spinning polyesters such as polylactide with an additive such as a polyurethane, glycolide, lactide, camphor, benzoic acid-2-hydroxyacetate, hexamethylbenzene, 1,2-cyclohexandione and other low molecular weight organic compounds which are preferably soluble in trichlormethane and/or dichlormethane and ethanol and having a melting temperature in the range of 40° to 180°C.

[0004] US-A-4983180 and US-A-4201216 are disclosures of sutures coated with a lubricant composition which can be stearic acid or calcium stearate. JP-A-4249527 discloses making the calcium salts of lactic and/or glycolic acid polymers. These calcium salts are said to be useful for the preparation of, inter alia, suture materials.

Summary of the Invention

[0005] It has now been found that fibers useful in making surgical sutures of improved performance can be prepared by extruding a composition containing an absorbable polymer and a plasticizer selected from the group consisting of stearic acid and its salts. This finding is the basis of the present invnetion, defined below, in Claim 1. Calcium stearate and stearic acid are particularly preferred plasticizers. In particularly useful embodiments the absorbable polymer is prepared from glycolide, glycolic acid, lactide, lactic acid and/or p-dioxanone.

Brief Description of the Drawings

[0006]

Fig. 1 is a schematic illustration of apparatus which is suitable for use in a preferred suture manufacturing process in accordance with the present invention.

Description of Preferred Embodiments

[0007] The filaments created in the method of the present invention are prepared by spinning or extruding a composition containing a bioabsorbable polymer and plasticizer.

[0008] The bioabsorbable polymer can be prepared from any of the monomers known to form biocompatible, bioabsorbable polymers, such as, for example, glycolide, glycolic acid, lactide, lactic acid, p-dioxanone, epsilon-caprolactone, alkylene carbonates and alkylene oxides. Polymers derived from glycolide, lactide, p-dioxanone or combinations thereof are preferred.

[0009] The plasticizers employed in this invention are selected from the group consisting of stearic acid and its salts. In particularly useful embodiments the plasticizer is stearic acid or calcium stearate.

[0010] For use in the method of the present invention, the absorbable polymer is in a granular, pellet or powder form. The polymer can be prepared in any manner and may, if necessary, be converted to the granular, pellet or powder form by any conventional means such as grinding, pulverizing, pelletizing or shredding. Polymerization techniques for preparing absorbable polymers are described for example in U.S. Patent Nos. 3,297,033; 4,052,988; 3,636,956; 4,605,730; 4,643,191; 4,653,497; 4,838,267; 5,007,923; 5,019,094; 5,047,048; and 5,037,950.

[0011] The absorbable polymer may be placed in a hopper and dried. An appropriate amount of plasticizer is then combined with the polymer and the polymer and plasticizer are mixed thoroughly to provide substantially uniform distribution of the plasticizer among the polymer particles or granules. The amount of plasticizer added may vary from 0.001 to 5 percent by weight based on the weight of the mixture. In particularly useful embodiments the amount of plasticizer employed is between 0.01 to 2 percent by weight. Most preferably, the amount of plasticizer is between 0.02 and 1 percent by weight.

[0012] The polymer and plasticizer can be mixed using any conventional technique, with or without heating. For example, a mechanical mixer, a static mixer or a combination of mixers may be employed to assist in providing a substantially uniform distribution of plasticizer and polymer. After mixing, the mixture is extruded or spun to form one or more filaments.

[0013] Known and conventional melt spinning apparatus can be used for the production of filaments, in accordance with this invention. Fig. 1 schematically illustrates a filament manufacturing operation in accordance with the invention. Extruder unit 10 is of a known or conventional type and is equipped with controls for regulating the temperature of barrel 11 in various zones thereof, e.g., progressively higher temperatures in three consecutive zones A, B and C along the length of the barrel. Pellets or powder of polymeric resin to be spun into filaments are introduced to the extruder through hopper 12. Prior to being placed in hopper 12, the polymer is combined and mixed with the plasticizer.

[0014] Motor-driven metering pump 13 delivers the polymer/plasticizer mixture at a constant rate through spinneret 15 possessing one or more orifices of desired diameter to provide a plurality of molten filaments 16. While spinneret 15 is shown schematically in Fig. 1 as extruding three filaments, it should be understood that the spinneret may extrude anywhere from 1 to 200 filaments simultaneously.

[0015] The filaments 16 travel downward and are gathered together by guide 19 to produce a yarn 17. The distance the filaments 16 travel after emerging from spinneret 15 to the point where they contact guide 19, i.e., the air gap, can vary and can advantageously be from about 0.5m to about 10m and preferably from about 1m to about 2m. A chimney 18, or shield, can be provided to isolate filaments 16 from contact by air currents which might otherwise affect the cooling or movement of the filaments in some unpredictable manner. In general, the temperature of zones A, B and C of the barrel 11 will vary depending on a number of factors such as the chemical nature of the polymer, the size of the powder or pellets, the nature and amount of plasticizer employed, and the rate of feed.

[0016] Once filaments 16 are gathered together by guide 19 to produce yarn 17, a spin finish may be applied to yarn 17. The spin finish is preferably applied to "as spun" filaments (i.e., to filaments which have not been drawn or otherwise treated, physically or chemically) which have been gathered into a yarn 17. The spin finish can be any desired spin finish composition and can be applied using any known technique. As seen in Fig. 1, the yarn 17 may be passed along the edge of applicator 20 to which the spin finished is supplied at a predetermined rate.

[0017] The yarn can be processed in any manner after the application of the spin finish. The spin finish will assist in holding the individual filaments together, thereby preventing entanglement or separation of the filaments during subsequent processing. The spin finish also provides lubrication between the yarn and any rollers or godets employed in subsequent processing. In addition, the spin finish will function as a heat transfer medium during subsequent processing, such as drawing, to provide more uniform heating of the yarn than can be achieved by simply passing the yarn through heated godets or heated air.

[0018] An example of subsequent processing is shown in Fig. 1. After application of the spin finish, the yarn may be wrapped around a lube godet 22 and one or more additional godets, for example, godet 23, to take up and adjust the tension on the yarn. The yarn 17 may then be passed to a heated draw frame 25. Draw frame 25 may be of any configuration. As shown in Fig. 1, draw frame 25 includes three pairs of godets which can be used to stretch the yarn or to allow relaxation and perhaps shrinkage of yarn 17. The speed at which the godets rotate and the temperature at which the draw frame is maintained will determine the amount of stretching and/or relaxation which occurs. Setting the various speeds and temperatures to achieve a desired result is within the purview of those skilled in the art.

[0019] Table I provides ranges of values for spinning and stretching parameters suitable for producing yarns from a composition containing a copolymer of glycolide and lactide and a plasticizer in accordance with the present invention.

TABLE I

MELT SPINNING APPARATUS AND OPERATING CONDITIONS	
Apparatus Component,	Copolymer of Glycolide and Lactide and Plasticizer
Operating Parameter	
Extruder barrel temp., zone A, °C	200-240
Extruder barrel temp., zone B, °C	210-250
Extruder barrel temp., zone C, °C	210-250
Extruder barrel pressure, MPa(psi)	4.82-10.34 (700-1500)
Extruder barrel melt temp., °C	210-260
Pump size, cc per rev.	16-.584
Pump rpm	10-40 for size .16
pump	
	3-11 size .584
pump	
Pump temp., °C	190-250
Pump pressure, MPa(psi)	3.45-10.34 (500-1500)
Pump melt temp., °C	190-250
Block temp., °C	200-250
Clamp temp., °C	200-250
Adapter temp., °C	200-250
Candle filter, screen, microns	10-60
No. of spinneret orifices	5-200
Diameter of spinneret orifices, mm, (.001 in)	0.127-0.762 (5-30)
Spinneret temp., °C	190-250
Spinneret pressure, MPa(psi)	3.45-17.23 (500-2500)
Spinneret melt temp., °C	190-250
cc/hr output, per spinneret orifice	1-80
First pair of godets, °C	50-90
First pair of godets, mpm	80-200
Second pair of godets, °C	60-120
Second pair of godets, mpm	300-1200
Draw (stretch) ratio	2-8
Third pair of godets, °C	ambient
Third pair of godets, mpm	250-1150
Shrinkage (relaxation), percent	3-10

[0020] After drawing, the yarn may then be sent to a winder where it can be placed onto spools for storage while awaiting further treatment or use.

[0021] The yarn may be formed into a surgical device using any known technique such as braiding, knitting, weaving,

air-entangling, twisting, tying, winding, or forming a composite using the yarn or pieces thereof as a reinforcing component.

EXAMPLES

[0022] The following Examples 1 and 2 show the preparation of a yarn from 27 filaments made from a poly(glycolide-colactide) (92.5:7.5 molar ratio; inherent viscosity 1.3-1.45 dl/g) plasticized with calcium stearate (Example 1) and stearic acid (Example 2). For comparison purposes, a control yarn of the same absorbable copolymer made by the same process but containing no plasticizer were also prepared. The spinning conditions for preparing the yarns of the Examples and the control are given in Table 2.

TABLE 2

	CONTROL	EXAMPLE 1	EXAMPLE 2
Resin Drying Conditions	10 hours at 100°C	10 hours at 100°C	10 hours at 100°C
Additive	None	Calcium stearate	Stearic Acid
Drying Conditions for additive	None	12 hours at 120°C	12 hours at 45°C
Percent of Additive	0.000	0.050	0.100
Spin Finish	20% Lurol in Iso-propanol		
Die	32 Holes	32 Holes	32 Holes
Pump c.c./rev	0.16	0.16	0.16
Filter (micron)	20	20	20
Barrel 1 (°C)	218	215	210
Barrel 2 (°C)	222	218	218
Barrel 3 (°C)	222	218	218
Clamp 1 (°C)	214	212	212
Mixer (°C)	214	212	212
Clamp 2 (°C)	214	212	212
Adaptor (°C)	210	210	210
Block (°C)	210	210	210
Pump (°C)	210	210	210
Die (°C)	212	210	214
Chimney (°C)	100	100	100
Chimney Air (°C)	109	110	110
Barrel Melt (°C)	218	215	215
Pump Melt (°C)	211	205	205
Die Melt (°C)	219	216	215
Screw RPM	1.8	8.5	8.4
Pump RPM	19.4	19.4	20.25
Lube Pump (ml/m)	0.20	0.20	0.20
Lube Godet (mpm)	133	134	134
Godet 1 (mpm)	137	138	136
Godet 2 (mpm)	767	769	772
Godet 3 (mpm)	750	751	750

TABLE 2 (continued)

	CONTROL	EXAMPLE 1	EXAMPLE 2
Barrel MPa(psi)	6.68 (970)	6.40 (929)	5.76 (835)
Pump MPa(psi)	6.89 (1000)	6.89 (1000)	6.89 (1000)
Die MPa(psi)	3.98 (577)	4.89 (710)	5.23 (758)
Average Denier	43.7	44.2	43.1
Average Tenacity	6.6	7.1	7.2
Average Elongation	21	20	21

[0023] The yarn was drawn 5.5 times and then twisted, combined and twisted again to form a cable-like suture. The cable was then annealed, post-washed and post-treated to remove any residual monomer or other vaporizable impurities. The processing of each of the yarns was essentially in accordance with the process described in U.S. Patent No. 5,019,093. The physical properties of the yarns were tested using the following procedures: PROCEDURES FOR MEASURING PHYSICAL PROPERTIES

Physical Property	Test Procedure
knot-pull strength, kg	U.S.P. XXI, (881) tensile strength, surgical suture
straight-pull strength, kg	ASTM D2256-88
elongation at break, %	ASTM D2256-88
tensile strength, kg/mm^2	ASTM D2256-88, Instron Corporation Model No. 1122
Tenacity	ASTM D2256-88
In Vitro Strength Retention	To simulate in vivo conditons, the suture samples were stored in a container filled with Sorenson's buffer solution at 37° C. After various period of time, the suture samples were then removed from the container to test their knot-pull strength, using an Instron tensile tester. In vitro knot-pull strength retention is indicative of in vivo strength retention.

[0024] The physical properties of suture fabricated from the control yarn and sutures made with plasticized filaments in accordance with this invention are presented in Table 3.

TABLE 3

	Plasticizer	Denier	Diameter (laser)	Straight-Pull Strength	Elongation at Break	Knot Pull Strength	Fiber Tenacity	In Vitro Strength rerention after 3 weeks
Example 1	Calcium Stearate	950	360mm	6.38 kg.	18.9%	3.54 kg	7.1 g/d	55%
Example 2	Stearic Acid	975	.354mm	5.97 kg.	16.7%	3.66 kg	7.2 g/d	49%
Control	None	963	.347mm	6.06 kg.	18.9%	3.31 kg.	6.6 g/d	44%

[0025] Monofilaments, rather than multifilament yarn, also can be formed in accordance with this invention. The monofilament may be used as sutures, or combined with other monofilaments to form a surgical article.

[0026] A suitable process for the manufacture of monofilament sutures of the present invention comprises the oper-

ations of melt extruding a mixture of resin and plasticizer at an extrusion temperature of from about 170°C to about 250°C to provide a monofilament, stretching the solidified monofilament at a temperature of from about 20°C to about 90°C in water (or other suitable liquid medium) or at from about 30°C to about 140°C in air (or other suitable gaseous medium) at a stretch ratio of from about 3:1 to about 10:1 to provide a stretched monofilament. ptionally, the stretched monofilament may be stretched again in air or other suitable gaseous medium preferrably at about 130°C. Preferably, the monofilament is then frozen at a temperature of from about -15°C to about 0°C. The suture may then be annealed at a temperature of from about 50°C to about 130°C to provide the finished suture.

[0027] Fig. 2A schematically illustrates a monofilament suture manufacturing operation which is especially suitable for producing larger size sutures, e.g., those of sizes 2/0 and larger. Extruder unit 110 is of a known or conventional type and is equipped with controls for regulating the temperature of barrel 111 in various zones thereof, e.g., progressively higher temperatures in three consecutive zones A, B and C along the length of the barrel. Pellets or powder of resins mixed with a plasticizer in accordance with the present invention are introduced to the extruder through hopper 112.

[0028] Motor-driven metering pump 113 delivers melt extruded resin mixture at a constant rate to spin pack 114 and thereafter through spinneret 115 possessing one or more orifices of desired diameter to provide a molten monofilament 116 which then enters quench bath 117, e.g., containing water, where the monofilament solidifies. The distance monofilament 116 travels after emerging from spinneret 115 to the point where it enters quench bath 117, i.e., the air gap, can vary and can advantageously be from about 0.5 to about 100 cm and preferably from about 1 to about 20 cm. If desired, a chimney (not shown), or shield, can be provided to isolate monofilament 116 from contact with air currents which might otherwise affect the cooling of the monofilament in an unpredictable manner. In general, barrel zone A of the extruder can be maintained at a temperature of from about 100°C to 220°C, zone B at from about 160°C to 230°C and zone C at from about 170°C to about 240°C. Additional temperature parameters include: metering pump block 113 at from about 170°C to about 230°C, spin pack 114 at from about 170°C to about 230°C, spinneret 115 at from about 170°C to about 230°C and quench bath at from about 10°C to about 80°C.

[0029] Monofilament 116 is passed through quench bath 117 around driven roller 118 and over idle roller 119. Optionally, a wiper (not shown) may remove excess water from the monofilament as it is removed from quench bath 117. On exiting the quench bath the monofilament is wrapped around a first godet 121 provided with nip roll 122 to prevent slippage which might otherwise result from the subsequent stretching operation; and subsequently wrapped around godets 101, 102, 103 and 104 or any other suitable godet arrangement. Monofilament 116 passing from godet 104 is stretched, e.g., with stretch ratios on the order of from about 3:1 to about 10:1 and preferably from about 4:1 to about 7:1, to effect its orientation and thereby increase its tensile strength.

[0030] In the stretching operation shown in Fig. 2A, generally suitable for larger size sutures, e.g., sizes 2 to 2/0, monofilament 116 is drawn through hot water (or other suitable liquid medium) draw bath 123 by means of godets 124, 105, 106, 107 and 108 or any other suitable arrangement of godets which rotate at a higher speed than godet 104 to provide the desired stretch ratio. The temperature of hot water draw bath 123 is advantageously from about 30°C to about 90°C and preferably is from about 30°C to about 50°C.

[0031] In the alternative stretching operation shown in Fig. 21B, generally preferred for smaller sutures sizes, e.g., sizes 3/0 to 8/0, monofilament 116 is drawn by godets 124, 105, 106, 107, and 108 or any other suitable godet arrangement through hot air convection oven chamber 123' at a temperature of from about 30°C to about 140°C and preferably from about 50°C to about 130°C to provide the desired amount of stretch. Following the stretching operation shown in Fig. 2A or 2B, monofilament 116 optionally may be subjected to an on-line annealing and/or additional stretching without shrinkage or relaxation with shrinkage operation as a result of which the monofilament shrinks. In the processes of Figs. 2A and 2B, on line annealing with or without relaxation when desired is accomplished by driving monofilament 116 by godets 126, 129, 130, 131, and 132 or any other suitable godet arrangement through second hot air oven chamber 125 at a temperature of from about 40°C to about 150°C and preferably from about 60°C to about 130°C. During the relaxation process, at these temperatures, monofilament 116 will generally recover to within about 80 to about 97 percent, and preferably to within about 95 percent, of its pre-annealed length to provide the finished suture. For relaxation, the third godet rotates at a slower speed than the second godet thus relieving tension on the filament.

[0032] Annealing of the suture also may be accomplished without shrinkage of the suture. In carrying out the annealing operation, the desired length of suture may be wound around a creel and the creel placed in a heating cabinet maintained at the desired temperature, e.g. about 60°C to about 130°C, as described in U.S. Patent No. 3,630,205. After a suitable period of residency in the heating cabinet, e.g., about 18 hours or so, the suture will have undergone essentially no shrinkage. As shown in U.S. Patent No. 3,630,205, the creel may be rotated within the heating cabinet in order to insure uniform heating of the monofilament or the cabinet may be of the circulating hot air type in which case uniform heating of the monofilament will be achieved without the need to rotate the creel. Thereafter, the creel with its annealed suture is removed from the heating cabinet and when returned to room temperature, the suture is removed from the creel, conveniently by cutting the wound monofilament at opposite ends of the creel. The annealed sutures, optionally attached to surgical needles, are then ready to be packaged and sterilized.

[0033] The suture of the present invention, suture 201, may be attached to a surgical needle 200 as shown in Fig. 3

by methods well known in the art. Wounds may be sutured by passing the needled suture through tissue to create wound closure. The needle preferably is then removed from the suture and the suture tied. EXAMPLE 3

[0034] A monofilament is made from a copolymer of glycolide and lactide containing about 18 weight percent glycolide and about 82 weight percent lactide. The resin is mixed with 3% by weight of calcium stearate and extruded into monofilaments of size using the following conditions:

CONDITIONS OF MANUFACTURING PLASTICIZED MONOFILAMENT

[0035]

Process Conditions	Extrusion Operation
extruder screw, rpm	2.2
pump rpm	12.7
driven roller, mpm	2.7
barrel temp., °C, zone A	115
barrel temp., °C, zone B	180
barrel temp., °C, zone C	183
clamp temp., °C	182
adapter temp., °C	183
pump temp., °C	183
barrel melt temp., °C	177
pump melt temp., °C	179
Spinneret melt temp., °C	180
barrel pressure, MPa(psi)	7.17 (1040)
pump pressure, MPa(psi)	3.44 (500)
pump size, cc per revolution	0.16
diameter of spinneret orifices, mm	1.25
no. of spinneret orifices	1
quench bath temp., °C	18
depth of driven roller, cm	19
	Stretching Orienting Operation
first draw oven temp, °C	126
first godet station, mpm	4.0
second godet station, mpm	22.4
second oven temp., °C	130
third godet station, mpm	29.5
draw ratio	7.4:1

[0036] For comparison purposes, a control monofilament was prepared using the same copolymer and the same extrusion and stretching conditions, however, the control monofilament was made without plasticizer. Both monofilaments were annealed at 90°C for 18 hours in a nitrogen oven.

[0037] The physical properties of the monofilament of Example 3 prepared in accordance with the present invention

and the control monofilament are presented in Table 4.

TABLE 4

	Knot-Pull MPa(kpsi)	Straight Pull MPa(kpsi)
Example 3	276 (40)	427 (62)
Control	234 (34)	414 (60)

[0038] As the data presented in Table 4 shows, the monofilament of Example 3 exhibited both higher knot-pull and straight-pull tensile strength compared to the control monofilament.

[0039] Obviously, other modifications and variations of the present invention are possible in light of the above teachings. For example, multifilament yarns may be formed rather than monofilaments.

[0040] The claims which follow identify embodiments of the invention additional to those described in detail above.

Claims

1. A method of improving the knot pull strength of a surgical suture, the method comprising:

   a. providing a mixture comprising a bioabsorbable polymer and a plasticizer selected from stearic acid and its salts;

   b. spinning or extruding at least one filament from said mixture; and

   c. forming the surgical suture from said at least one filament; wherein said step of providing a mixture comprises:

      i. providing particles of the bioabsorbable polymer;

      ii. combining said plasticizer with said particles; and

      iii. mixing the particles and plasticizer together to provide a substantially uniform distribution of plasticizer among the particles.

2. A method as in claim 1 wherein said plasticizer is selected from stearic acid and calcium stearate.

3. A method as in claim 1 or 2, wherein said bioabsorbable polymer is selected from polymers made from one or more of glycolide, glycolic acid, lactide, lactic acid, epsilon-caprolactone and p-dioxanone.

4. A method as in claim 1, 2 or 3, wherein said copolymer is a block copolymer.

5. A method as in any one of the preceding claims, wherein said plasticizer is present in said mixture in an amount from 0.001 to 5 percent by weight.

6. A method as in claim 5 wherein said plasticizer is present in said mixture in an amount from 0.02 to 1 percent by weight.

Patentansprüche

1. Verfahren zum Verbessern der Knotenzugfestigkeit eines chirurgischen Nahtmaterials, umfassend:

   a. Herstellen einer Mischung umfassend ein bioabsorbierbares Polymer und einen Weichmacher, der aus Stearinsäure und ihren Salzen ausgewählt ist;

   b. Spinnen oder Extrudieren von zumindest einem Filament aus der Mischung; und

   c. Bilden des chirurgischen Nahtmaterials von dem zumindest einen Filament; wobei der Schritt des Herstel-

lens einer Mischung umfaßt:

i. Bereitstellen von Partikeln des bioabsorbierbaren Polymers;

ii. Zusammenbringen des Weichmachers mit den Partikeln; und

iii. Mischen der Partikel und des Weichmachers, um eine im wesentlichen gleichmäßige Verteilung des Weichmachers unter den Partikeln zu erzeugen.

2. Verfahren gemäß Anspruch 1, wobei der Weichmacher aus Stearinsäure und Calciumstearat ausgewählt wird.

3. Verfahren gemäß Anspruch 1 oder 2, wobei das bioabsorbierbare Polymer aus Polymeren ausgewählt ist, die aus einem oder mehreren von Glycolid, Glycolsäure, Lactid, Milchsäure, Epsilon-Caprolacton und p-Dioxanon ausgewählt sind.

4. Verfahren gemäß Anspruch 1, 2 oder 3, wobei das Copolymer ein Block-Copolymer ist.

5. Verfahren gemäß einem der vorhergehenden Ansprüche, wobei der Weichmacher in der Mischung in einer Menge von 0,001 bis 5 Gew-% vorhanden ist.

6. Verfahren gemäß Anspruch 5, wobei der Weichmacher in der Mischung in einer Menge von 0,02 bis 1 Gew-% vorhanden ist.

Revendications

1. Méthode d'amélioration de la résistance à l'étirement du noeud d'une suture chirurgicale, la méthode comprenant :

a. fourniture d'un mélange comprenant un polymère bioabsorbable et un plastifiant sélectionné parmi l'acide stéarique et ses sels ;
b. filage ou extrusion d'au moins un filament à partir dudit mélange ; et
c. formation de la suture chirurgicale à partir dudit au moins un filament ; où ladite étape de fourniture d'une mélange comprend :

i. fourniture de particules du polymère bioabsorbable ;
ii. combinaison dudit plastifiant avec lesdites particules ; et
iii. mélange des particules et du plastifiant ensemble pour fournir une distribution substantiellement uniforme du plastifiant parmi les particules.

2. Méthode selon la revendication 1, dans laquelle ledit plastifiant est sélectionné parmi l'acide stéarique et le calcium stéarate.

3. Méthode selon la revendication 1 ou 2, dans laquelle ledit polymère bioabsorbable est sélectionné parmi des polymères faits de un ou plus parmi un glycolide, de l'acide glycolique, un lactide, l'acide lactique, l'epsilon-caprolactone et la p-dioxanone.

4. Méthode selon la revendication 1, 2 ou 3, où ledit copolymère est un copolymère bloc.

5. Méthode selon l'une quelconque des revendications précédentes, dans laquelle ledit plastifiant est présent dans ledit mélange en une quantité de 0,001 à 5 pour cent en poids.

6. Méthode selon la revendication 5, dans laquelle ledit plastifiant est présent dans ledit mélange en une quantité de 0,02 à 1 pour cent en poids.

FIG. 1